IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN PHARMACEUTICALS INC.	)	
Defendant.	)	

COMPLAINT

Plaintiffs The Research Foundation of State University of New York; New York University; Galderma Laboratories Inc.; and Galderma Laboratories, L.P. (collectively, "Plaintiffs"), for their Complaint against Defendant Mylan Pharmaceuticals Inc., hereby allege as follows:

Parties

1. Plaintiff The Research Foundation of State University of New York (hereinafter, "RF") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business at 35 State Street, Albany, New York 12207.

2. Plaintiff New York University (hereinafter, "NYU") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a place of business at 70 Washington Square South, New York, New York 10012.

3. Plaintiff Galderma Laboratories Inc. (hereinafter, "GLI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

4. Plaintiff Galderma Laboratories, L.P. (hereinafter, "GLLP") is a privately held partnership registered in the state of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

5. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. (hereinafter, "Mylan") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Nature of the Action

6. This is a civil action for infringement of United States Patents Nos. 7,232,572 ("the '572 patent"); 7,211,267 ("the '267 patent"); 5,789,395 ("the '395 patent"); and 5,919,775 ("the '775 patent"). (Exhibits A-D.) This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Mylan has previously availed itself of this forum for purposes of litigating its patent disputes. For example, in 2002, Mylan filed a patent

infringement lawsuit in *Mylan Pharmaceuticals Inc. v. Kremers Development Company et al.*, C.A. No. 02-1628 (D. Del.). Mylan has also submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Mylan admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc., et al. v. Dr. Reddy 's Laboratories, Inc., et al.*, C.A. No. 08-52 (D. Del.); *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals, Inc.*, C.A. No. 07-805 (D. Del.); *Sciele Pharmaceuticals v. Mylan Pharmaceuticals Inc.*, C.A. No. 07-664 (D. Del.); *Sanofi-Aventis, et al. v. Actavis, et al.*, C.A. No. 07-572 (D. Del.); *Boehringer Ingelheim International GMBH, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-854 (D. Del.); *Janssen Pharmaceutica N.V., et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-371 (D. Del.); and *AstraZeneca LP, et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 08-453 (D. Del.).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-In-Suit

10. GLLP holds New Drug Application ("NDA") No. 50-805 on Oracea® brand doxycylcine capsules, and is the exclusive distributor of Oracea® in the United States.

11. On June 19, 2007, the '572 patent, entitled "Methods of Treating Rosacea" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. as assignee. A copy of the '572 patent is attached as Exhibit A.

12. The '572 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

13. GLI is the current assignee of the '572 patent.

14. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '572 patent.

15. On May 1, 2007, the '267 patent, entitled "Methods of Treating Acne" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. as assignee. A copy of the '267 patent is attached as Exhibit B.

16. The '267 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

17. GLI is the current assignee of the '267 patent.

18. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '267 patent.

19. On August 4, 1998, the '395 patent, entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production" was duly and legally issued to RF and Hospital for Joint Diseases (a predecessor in interest to NYU) as assignees. A copy of the '395 patent is attached hereto as Exhibit C.

20. The '395 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

21. GLI is the licensee of the '395 patent.

22. Plaintiffs have the right to sue and recover for any infringement of the '395 patent.

23. On April 16, 1998, the '775 patent, entitled "Method for Inhibiting Expression of Inducible Nitric Oxide Synthase with Tetracycline" was duly and legally issued to RF and Hospital for Joint Diseases (a predecessor in interest to NYU) as assignees. A copy of the '775 patent is attached hereto as Exhibit D.

24. The '775 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

25. GLI is the licensee of the '775 patent.

26. Plaintiffs have the right to sue and recover for any infringement of the '775 patent.

Acts Giving Rise to this Action

Count I – Infringement of the '572 Patent

27. Plaintiffs restate Paragraphs 1-26 as if fully set forth herein.

28. Upon information and belief, Defendant Mylan submitted ANDA No. 90-855 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)).

29. ANDA No. 90-855 seeks FDA approval for the commercial manufacture, use and sale of generic doxycycline delayed-release capsules, 40mg, for oral administration ("the Generic Products").

30. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA Mylan alleged in ANDA No. 90-855 that claims of the '572 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

31. ANDA No. 90-855 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '572 patent.

32. Plaintiffs received written notification of ANDA No. 90-855 and its § 505(j)(2)(A)(vii)(IV) allegations on or about February 4, 2009.

33. Mylan's submission of ANDA No. 90-855 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '572 patent under 35 U.S.C.

§ 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '572 patent under 35 U.S.C. § 271(a), (b) and/or (c).

34. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

35. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '572 patent at the time of the submission of ANDA No. 90-855 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that the filing constituted infringement of that patent.

Count II – Infringement of the '267 Patent

36. Plaintiffs restate Paragraphs 1-35 as if fully set forth herein.

37. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan alleged in ANDA No. 90-855 that claims of the '267 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

38. ANDA No. 90-855 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '267 patent.

39. Mylan's submission of ANDA No. 90-855 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '267 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '267 patent under 35 U.S.C. § 271(a), (b) and/or (c).

40. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

41. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '267 patent at the time of the submission of ANDA No. 90-855 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that the filing constituted infringement of that patent.

Count III – Infringement of the '395 Patent

42. Plaintiffs restate Paragraphs 1-41 as if fully set forth herein.

43. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan alleged in ANDA No. 90-855 that claims of the '395 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

44. ANDA No. 90-855 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '395 patent.

45. Mylan's submission of ANDA No. 90-855 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '395 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '395 patent under 35 U.S.C. § 271(a), (b) and/or (c).

46. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

47. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '395 patent at the time of the submission of ANDA No. 90-855 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that the filing constituted infringement of that patent.

Count IV – Infringement of the '775 Patent

48. Plaintiffs restate Paragraphs 1-47 as if fully set forth herein.

49. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan alleged in ANDA No. 90-855 that claims of the '775 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

50. ANDA No. 90-855 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '775 patent.

51. Mylan's submission of ANDA No. 90-855 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '775 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '775 patent under 35 U.S.C. § 271(a), (b) and/or (c).

52. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

53. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '775 patent at the time of the submission of ANDA No. 90-855 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that the filing constituted infringement of that patent.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Mylan has infringed the '572, '267, '395, and '775 patents;

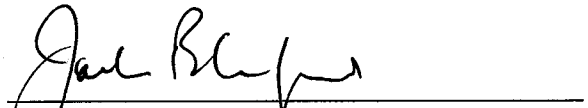
B. That, pursuant to 35 U.S.C. § 271(e)(4) (A), the effective date of any approval of ANDA No. 90-855 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '572, '267, '395, and '775 patents, including any extensions;

C. That Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '572, '267, '395, and '775 patents, including any extensions;

D. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP



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